

EXHIBIT

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UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/545,591	11/13/95	JONSSON	S C-35299

34M1/0321

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EXAMINER

SOOHOO, T

ART UNIT

PAPER NUMBER

3405

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DATE MAILED: 03/21/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/545,591	Applicant(s) Jonason
	Examiner Tony Soohoo	Group Art Unit 3405

Responsive to communication(s) filed on Nov 13, 1996
 This action is FINAL.
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1 and 7-18 is/are pending in the application.
 Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 1 and 7-18 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on Nov 13, 1995 is/are objected to by the Examiner.
 The proposed drawing correction, filed on Nov 13, 1995 is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____.
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 *Certified copies not received: _____
 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

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... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

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1. Since the papers filed in the national stage application has failed provide a request for a continuation - in - part application under 37 CFR 1.62 for a national application filed under 35 USC 111(a), the substitute specification filed on 11/13/95 in the amendment entitled "Voluntary Preliminary Amendment" (paper no. 5) has been considered as not being part of the original specification within the national stage application as filed under 35 USC 371.

Additionally, since the originally filed papers has failed to provide an oath or declaration under 37 CFR 1.62(c) which identifies the substitute specification of 11/13/95 as a preliminary amendment (for a c-i-p) which the inventor(s) has "reviewed and understands" under 37 CFR 1.63, (See MPEP 608.04(b)), the substitute specification has not been considered as an original part of the original disclosure.

2. Accordingly, the substitute specification and substitute drawings filed with the amendment titled "Voluntary Preliminary Amendment" (paper no. 5) filed on 11/13/95 has not been entered as a *substitute specification* because 1) it introduces new matter into the disclosure, 2) fails to provide a statement that no new matter has been entered, and 3) Applicant has failed conform to MPEP § 608.01(q), which requires the submission of a marked-up copy which shows additions to and/or deletions from the original specification (as filed in the PCT national stage application, filed under 35 USC 371).

3. Under current practice, substitute specifications may be voluntarily filed by the Applicant if desired. A substitute specification will normally be accepted by the Office even if it has not been required by the Examiner. Substitute specifications will be accepted if Applicant submits therewith a marked - up copy which shows the portions of the original specification which are being added and deleted and a statement that the substitute specification includes no new matter and that the substitute specification includes the same changes as are indicated in the marked - up of the original specification showing additions and deletions. Such statement must be a

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verified statement if made by a person not registered to practice before the Office. Additions should be clearly indicated in the marked - up copy such as by underlining, and deletions should be indicated between brackets. Examiners may also require a substitute specification where it is considered to be necessary. Also see 37 CFR 1.118.

4. 37 CFR 1.118. Amendment of disclosure.

(a) No amendment shall introduce new matter into the disclosure of an application after filing date of the application (§ 1.53(b)). All amendments to the specification, including the claims, and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition to the original disclosure, cannot be added to the application after its filing date even though supported by an oath or declaration in accordance with § 1.63 or § 1.67 filed after the filing date of the application.

(b) If it is determined that an amendment filed after the filing date of the application introduces new matter, claims containing new matter will be rejected and deletion of the new matter in the specification and drawings will be required even if the amendment is accompanied by an oath or declaration in accordance with § 1.63 or § 1.67.

5. However, it is noted that the amendment to the claims of the preliminary amendment filed on 11/13/95 has been entered. The status of the claims are: Claims 1 and 7-18 as amended or added by the preliminary amendment of 11/13/95; Claims 2-6 has been canceled by the preliminary amendment of 11/13/95.

6. Consequently, since the substitute specification has not been entered, the Second Filed preliminary Amendment filed 11/13/96 (filed one year later from the filed papers of 11/13/95) has not been entered since the directions for entry of the second filed preliminary amendment do not correspond to the page and line numbers of the instant (original) disclosure thereby the amendment can not be entered.

7. An Office Action upon the original disclosure and drawings, as filed as a national stage application filed under 35 USC 371, and the amended claims 1,7-18 (as instructed in the paper no. 5, filed 11/13/95) follows:

DETAILED ACTION

Drawings

8. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

9. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/13/95 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.118 states that matter involving a departure from or an addition to the original disclosure cannot be added to the application after its filing date. The original disclosure does not support the showing of the elements and configuration of Figures 7-13.

10. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown and clearly labeled with a reference number in the drawings:

- a. The features claimed in claim 8;
 - i. The top, and top end of the cylindrical inner container;
 - ii. The top and top end of the outer container;
 - iii. The "interlocking cover" of the outer container (10);
 - iv. The depending edge of the interlocking cover;
 - v. The treaded internal surface of the interlocking cover;
 - vi. The treads of the outer container;
 - vii. The treaded and centrally located throughbore of the outer container;
 - viii. The cylindrical collar (claim 8, line 29, is this the cylindrical part 12a on the left side or is the element 12b? Also see page 6, line 19?);
 - ix. The cylindrical collar top portion and bottom portion (the duct 16?);

x. The threaded portion of the outside surface of the cylindrical collar bottom portion;
xi. The grooved annular flange of the top portion of the outside surface;
xii. The O-ring (the annular seal as referred in the disclosure?);
xiii. The annular upstanding lip encircling the throughbore;
xiv. The cap as recited on claim 8, page 17, line 16;
xv. The threads of the outside of the cap;
xvi. The opening of the cap;
xvii. The neck member of the funnel shaped portions of the end of the containers;

and the following elements must be identified or shown:

xviii. The grooved annular flange at the top portion of the cylindrical collar of claim 11;
xix. The threaded portion of the inside portion of the top portion of the cylindrical collar of claim 11;
xx. The brush like devices of claim 7;

The above must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

11. The drawings are objected to because in Figure 1, element 12d has been labeled as 12a, see the top right side of figure 1. Correction is required.

12. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 9b and 11b. Correction is required.

13. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: The reference letter "A". Correction is required.

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97-1.99.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (i) Abstract of the Disclosure.

14. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification must provide proper antecedent basis within the specification for the particular names of the elements used in the claim language itself. For example; in claims 7-12, the top end, the bottom end, the throughbore, the cylindrical collar having the top portion, the

bottom portion, the inside surface, outside surface, the grooved flange, the O-ring, the annular upstanding lip, the interlocking cover, the cap, the internal passaged in the filter, the annular upstanding lip, the annular seat, the annular groove. The above are exemplary only. Applicant is advised to review all terminology used in the claims and appropriately provide proper antecedent basis of such terminology within the specification.

15. The disclosure is objected to because of the following informalities:

The specification fails to provide a description of the drawings.

The specification fails to provide proper headings, see the "Arrangement of the Specification" above.

Appropriate correction is required.

16. The amendment filed 11/13/95 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The invention as described by the claims 12-18 including a tightening rod within a tubular rod and its operation.

Applicant is required to cancel the new matter in the response to this Office action.

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. The specification is objected to under 35 U.S.C. 112, first paragraph, as
1) the specification, as originally filed, does not support the invention as is now claimed,
2) failing to provide an adequate written description of the invention, and 3) failing to adequately teach how to make/use the invention, i.e. failing to provide an enabling disclosure.

The specification fails to support the operation of a tightening rod within the tubular rod and its operation within the device as recited in claims 12-18.

Also, the specification fails to provide an adequate written description describing and identifying the interlocking cover; the threads of the elements; the top and bottom ends of the elements; the throughbore, the cylindrical collar with its groove, flange and treads; the cap; and the frictional contact and/or seals between the funnel-shaped elements and the O-ring with the cover, annular seat, and annular upstanding lip; and the internal passages of the filter.

Furthermore the specification, as presently understood by the Examiner, fails to adequately teach how to make/use the invention, i.e. failing to provide an enabling disclosure since it is unclear how cement powder may be provided into the space 15 between the inner and outer container, see fig 1, element B. The Examiner questions manner in which the powder may be added into the space. It appears that the addition of powder B into the chamber area 15 since removal the inner container 9 would result in an opening in the neck portion of the outer container 10. If the powder is added into the space 15 by removing the threaded cap (near 10b), the inner container 9 must also be removed due to the flange and boss arrangement at 16, 17 thereby causing an opening in the neck so that the powder escapes. Therefore the disclosure appears to be incomplete and non-enabling in teaching how to make the final product of the claimed a device whereby the powder is provided in the recited space 15. For the same reasons as stated, the disclosure also appears to be non-enabling in the claimed method, in particular with the step of providing the bone cement powder into the space, since it is presently unclear to the Examiner how the bone cement powder may be provided within the space structure.

Claim Objections

19. Claims 10-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The depending claims 10-12 appear to fail to limit the subject matter of the parent claim 8 since it appears that:

Claim 10 appears to re-introduce and re-claim the element of the annular upstanding lip encircling the troughbore of claim 8, page 17, line 9;

Claim 11 appears to re-introduce and re-claim the element of the grooved flange receiving an O-ring of claim 8, page 17, line 7;

Claim Rejections - 35 USC § 112

20. Claims 1,7-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as presently understood by the Examiner, fails to teach how to make/or use the device whereby a powered material is provided in to the space between the inner wall of the outer container and the inner container, see remarks above in regards to the addition of powder and the cooperation of the elements of the neck and the inner and outer container. Also, the specification fails to describe the invention and cooperation of elements as recited in claims 12-18 including a tightening rod within a tubular rod and its operation within the invention.

21. Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The claims use terminology which fail to have antecedent basis in the body of the specification thereby rendering the claimed subject matter in which Applicant regards as the invention as being unclear within the language of the claim. Some examples are: "interlocking cover", "cylindrical collar", "O-ring", "a cap", "grooved flange", "annular upstanding lip", "annular flange", "annular seat".

Claim 8 is incomplete, or misleading and unclear in the structural cooperation between the glass ampule containing the liquid component within the device. In reference to the last paragraph of claim 8, the claim language appears to state that the rotation of the cylindrical collar causes a separation of the inner and outer containers so that the powder and the liquid component is released concurrently into the mixing vessel, i.e. the liquid component is released when the collar is twisted in the second direction of rotation.

As seen in figures 2 and 5, the liquid component is released prior to the rotative separation of the inner and outer containers 9, 10 as seen in figure 3. Therefore, it appears that the claim is misleading to state that the liquid component is released from the ampule during the rotation in the second direction (during the separation of the inner and outer containers). Furthermore, it appears that the claim is incomplete where it fails to point out that the ampule releases the liquid component when the rotation of the cap (12b as best understood presently by the Examiner) rotated in a first direction to lower the cap (12b?) relative to the inner container 9, (see figures 1-2, and 4-5 especially the lower location of the receiving hole {unnumbered} of the pin 12c in figures 2 and 5).

The claimed language is inconsistent in the naming of elements thereby rendering the claim to be unclear and failing to provide proper antecedent basis for recited elements. Examples are: "said top end, (page 16, line 8; note that a 'top' has been referred to but not the term 'top

end'), "said grooved flange (page 17, line 7, 'grooved, annular flange' has been established), "said annular upstanding lip encircling said throughbore (page 17, line 9), "said frictional contact (page 17, line 19), "the sealing contact (page 17, line 24)", "said lip, (page 18, line 11)". The above are exemplary only. Applicant is advised to review all terminology and amend as necessary to provide proper antecedent basis for the same element within the invention.

Claim 8 is narrative and fails to positively point out the shape of the inner and outer container top ends as being a funnel shape. The phrase "which are funnel shaped..." page 17, line 16, is narrative and fails to positively point out the shape.

Claim 8 is unclear in operation and fails to point out what Applicant regards at the invention by the recitation of (page 17, lines 19-21) "said frictional contact creating a seal therebetween such that power component is prevented from discharging out of said container." The claim should point out that the powder is prevented from discharging out of the neck portion of the container.

Claim 8 is vague and unclear in what reference is made by "the sealing contact" in page 17, line 24. Is this the seal contact between the O-ring 17 and the interlocking cover? Or is this seal between the two neck portions being in frictional contact?

Depending claim 7 is unclear and vague in the position and cooperation of the brush-like devices on the inner container. The claim is vague in the "arrangement" of the brushes "so arranged" to assist in the recited release of powder.

Claim 9 points out that the ampule is broken but the claims fail to point out a mode of operation of the device which breaks the ampule. It is noted that claim 8 points out that the ampule is sealed, but however, fails to positively point out that the ampule is broken during the operation of the invention.

Claims 10-12 appears to re-introduce elements and cooperation between elements which were previously claimed in claim 8. This renders the claim unclear in what Applicant regards as the invention.

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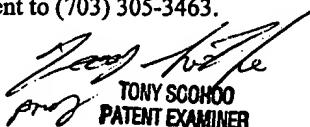
22. The claims have been examined as best understood by the Examiner.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Faccioli et al 5193907, 5435654, and corresponding German patent 4030832 and British patent 2239818 disclose inner and outer containers for mixing a bone cement process. The patents to Nilson et al 5252301, Chan 4973168, and Krenziger 4952065 discloses mixing chambers for viscous materials.

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Tony Soohoo whose telephone number is (703) 308-2882.

Please direct all written correspondence for this application to Art Unit 3405. Any telephone status inquiries regarding this application should be directed to (703) 308-0861. Facsimile correspondence for this application should be sent to (703) 305-3463.


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TGS/
March 14, 1997